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(71) Applicant: **MISUZU INDUSTRIES CORPORATION**
3090 Ooazashiga
Suwa-shi, Nagano-ken(JP)

Applicant: **Yamazaki, Kenji**
2-477-RC1-201, Uwano
Nagano-shi, Nagano-ken(JP)

(72) Inventor: **Yamazaki, Kenji**
2-477-RC1-201, Uwano
Nagano-shi, Nagano-ken(JP)

(74) Representative: **Schmitz, Hans-Werner, Dipl.-Ing. et al**
Hoefer, Schmitz, Weber,
Ludwig-Ganghofer-Strasse 20
W-8022 Grünwald bei München(DE)

(54) Auxiliary artificial heart of the embedded-in-body type.

(57) An auxiliary artificial heart embedded in the human body. The auxiliary artificial heart has an apex cordis area ring (2) and a body (3). The apex cordis area ring (2) is embedded in a cut-out apex cordis area (C) of the human heart. The body (3) includes an elongated pump section (4) and a drive section (5). The pump section (4) is inserted into one of the ventricles (B, J) of the human heart, passing through the apex cordis area ring (2). A front end nozzle (7) whose diameter is smaller than that of the pump section (4) is formed at the front end of the pump section (4), and it is inserted into the aorta or pulmonary artery (G or L), passing through the center of the aorta or pulmonary valve (F or K). The pump section (4) sucks blood in the ventricle through its base portion and feeds it into the aorta or pulmonary artery through the front end nozzle (7).

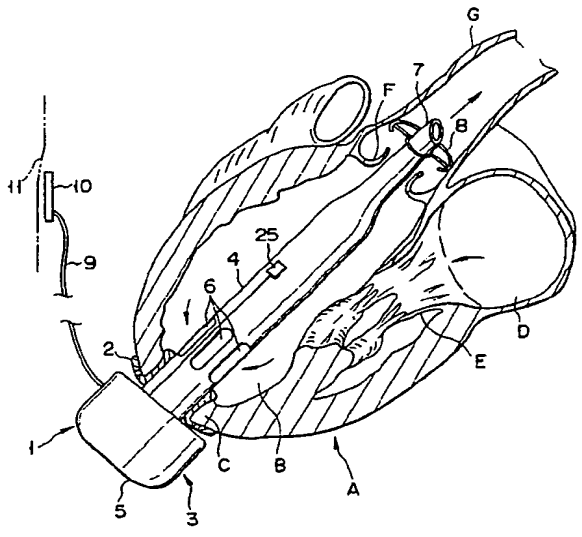

FIG. 1

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The present invention relates to an auxiliary artificial heart of the embedded-in-body type embedded in the left or right ventricle of the heart of a human body.

More particularly, it relates to an auxiliary artificial heart intended to feed blood by a pump in addition to blood fed by the human heart, without damaging the function of the human heart.

The conventional artificial hearts of the embedded-in-body type include those of the diaphragm, sack, centrifugal, pusher plate and other systems.

However, these artificial hearts are intended to feed blood, using the human heart as a bypass or instead of the human heart. They are therefore large in size and not suitable for their being embedded in the human body. When the artificial heart is large in size, the patient who has the artificial heart embedded in his or her heart must bear large burden. In addition, that area of the artificial heart which is contacted with blood becomes large, thereby causing thrombus.

Further, it is asked that the artificial heart is made high in durability and reliability. The conventional artificial hearts are complicated in structure and they have a limitation in enhancing their durability and reliability.

In addition to these artificial hearts intended to feed blood, using the human heart as a bypass or instead of the human heart, there is another artificial heart of such a type as disclosed in an essay "In Vivo Evaluation Of A Peripheral Vascular Access Axial Flow Blood Pump" reported by Richard K. Wampler et al on pages 450 - 454 of "TRANS AM SOC ARTIF INTERN ORGANS" Vol. XXXIV (1988).

This artificial heart has a small-sized pump inserted into the artery and a tube is attached to a sucking opening of the pump. The tube is inserted into the ventricle of the human heart, passing through the artery valve. Blood in the ventricle is sucked through the tube and fed into the artery. This artificial heart hardly damages the function of the human heart and it can feed blood in addition to blood fed by the human heart.

The pump must be small in size to insert it into the artery. To meet this requirement, the pump in the above-mentioned artificial heart excludes a driving motor from it. The driving motor is arranged on the external of the human body, and the driving force is supplied from the motor through a wire to it. Due to such an arrangement, not only the movement of the patient is restricted while the artificial heart is operating, but also the patient cannot carry the artificial heart for a long time.

A first object of the present invention is to provide an auxiliary artificial heart capable of feeding blood into the artery by a pump in addition to blood fed by the human heart without damaging the function of the human heart and disturbing the flow of blood in the artery.

Another object of the present invention is to provide an artificial heart smaller in size and lighter in weight.

A further object of the present invention is to provide an artificial heart higher in durability and reliability.

These and other objects as well as merits of the present invention can be achieved by the following examples of the artificial hearts according to the present invention.

An example of the artificial heart according to the present invention has an apex cordis area ring embedded in a cut-out apex cordis area of the human heart, and an artificial heart body. The apex cordis area ring is embedded in that area of the apex cordis of the human heart which has been cut out. The body is inserted into one of the ventricles of the human heart, passing through the apex cordis area ring.

The body comprises a pump section and a drive section for driving the pump section. The pump section is shaped like a cylinder and it has a front end nozzle, whose diameter is smaller than its diameter, at its front end. It is inserted into the right or left ventricle of the human heart, passing through the apex cordis area ring. The drive section is preferably located outside the human heart. The front end nozzle is inserted into the aorta or pulmonary artery, passing through the center of the aorta or pulmonary valve.

The pump section is driven by a motor in the drive section to suck blood in the ventricle through the base portion thereof and fed it into the aorta or pulmonary artery through the front end nozzle. The front end nozzle has a relatively small diameter. Even when it is inserted into the aorta or pulmonary artery, passing through the aorta or pulmonary valve, therefore, it hardly damages the aorta or pulmonary valve.

This artificial heart can feed blood in the ventricle into the aorta or pulmonary artery without adding any influence to the function of the human heart, as described above. This enables a sufficient amount of blood to be fed into the aorta or pulmonary artery by the artificial heart as well as by the beating human heart. Further, the body of the auxiliary artificial heart is inserted into the ventricle and only a part of the front nozzle is inserted into the artery. This prevents the flow of blood in the artery from being disturbed by the artificial heart. According to this example of the artificial heart of the present invention, the drive section which includes a motor and the like is located outside the human heart and it is only the pump section that is inserted into the ventricle. The volume of this pump

section can be made relatively small or smaller than that of the ventricle obtained when it shrinks to the greatest extent. Therefore, the natural function of the human heart cannot be damaged by this pump section. Furthermore, the artificial heart adds no influence to the natural function of the human heart, as described above, even if it should get out of order. The amount of blood fed by the beating human heart can be thus still guaranteed, thereby preventing the occurrence of sudden death.

According to this example of the artificial heart, the pump section includes a screw pump of the axial-flow type. This screw pump can be made simpler in construction and smaller in size while providing it with higher durability and reliability.

According to this example of the artificial heart, the drive section is controlled by a control means, depending upon the state of the human heart or the number of its beats, the blood pressure in it and the like, so as to effectively assist its function.

According to another example of the artificial heart of the present invention, the front end nozzle is tilted relative to the pump section to match an angle which is formed by the axial direction of the ventricle and that of the artery. Further, the front end of the front end nozzle is held in the center of the artery or artery valve by a positioning ring. The front end nozzle is thus held at a predetermined position relative to the artery valve not to add any influence to the function of the artery valve.

This invention can be more fully understood from the following detailed description when taken in conjunction with the accompanying drawings, in which:

Fig. 1 shows the whole of a first example of the artificial heart according to the present invention embedded in the left ventricle of the human heart;

Fig. 2 is a vertically-sectioned view showing the artificial heart;

Fig. 3 is a vertically-sectioned view showing a variation of the screw pump;

Fig. 4 is a vertically-sectioned view showing another variation of the screw pump;

Fig. 5 is a vertically-sectioned view showing a further variation of the screw pump;

Fig. 6 is a vertically-sectioned view showing the pump section of a second example of the artificial heart according to the present invention;

Fig. 7 is a sectional view taken along a line VII - VII in Fig. 6;

Fig. 8 is a sectional view taken along a line VIII - VIII in Fig. 6;

Fig. 9 is a sectional view taken along a line IX - IX in Fig. 6;

Fig. 10 is a side view showing a third example of the artificial heart according to the present invention;

Fig. 11 shows the artificial heart of the present invention embedded in the right ventricle of the human heart;

Fig. 12 is a vertically-sectioned view showing a part of the pump section of a fourth example of the artificial heart according to the present invention; and

Fig. 13 is a vertically-sectioned view showing a part of a variation of the pump section.

Figs. 1 through 5 show a first example of the artificial hear according to the present invention. Fig. 1 shows the artificial heart of the present invention embedded in the left ventricle B of the heart A of the human body. Capital letter C denotes an apex cordis area, D a left atrium, E a mitral valve, E an aorta valve and F an aorta.

This artificial heart 1 comprises an apex cordis area ring 2 and an artificial heart body 3.

The apex cordis area ring 2 is a short cylinder provided with a collar and it is fitted into the cut-out apex cordis area C of the heart A, passing through this area C.

The artificial heart body 3 comprises a pump section 4 and a drive section 5 for driving the pump section 4. The pump section 4 is a relatively small-sized cylinder, in which a smaller-sized pump of the axial-flow type is housed. The pump section 4 has a nozzle 7, which has a smaller diameter, at the front thereof. The pump section 4 is inserted into the left ventricle B, passing through the apex cordis area ring 2. The pump section 4 is sealed relative to the apex cordis area ring 2 by the well-known seal means to prevent blood from being leaked outside. The front end nozzle 7 of the pump section 4 is inserted into the aorta G, passing through the center of the aorta valve F. The drive section 5 is preferably embedded in the human body outside the heart A, as seen in the case of this example.

A positioning ring 8 is fitted onto the front end of the front end nozzle 7. The positioning ring 8 is located in the aorta G and serves to position the front end nozzle 7 at the center of the aorta G or aorta valve F and hold it there.

A motor, a control means, a battery and the like are housed in the drive section 5, which is connected to an electrode 10 of the non-contact type through a line 9, and the electrode 10 is embedded in the human body near the skin H thereof.

According to the artificial heart 1 arranged as described above, the pump section 4 is driven by the drive section 5 to suck blood in the left ventricle B through plural slits 6 at the base thereof and pressure-feed it into the aorta G through the front end nozzle 7.

The volume of the pump section 4 is relatively small and smaller than that of the left ventricle B

obtained when it is shrunk to the greatest extent. Even when the pump section 4 is inserted into it, therefore, the pump section 4 adds no influence to it. Further, the front end nozzle 7 is small in diameter and passes through the center of the aorta valve F. This prevents the front end nozzle 7 from adding any influence to the function of the aorta valve F. Assisting the function of the heart A of the human body without adding any influence to it, therefore, this artificial heart feeds blood in addition to that blood which is fed by the heart of the human body to thereby keep the amount of blood enough to be fed into the aorta G.

The arrangement and operation of the artificial heart body 3 will be described in more detail with reference to Figs. 1 and 2.

The pump section 4 has a cylindrical metal casing 12 and the drive section 5 also has a metal casing 13. A motor 15 is housed in the drive section 5. DC, ultrasonic and other motors can be used as the motor 15. A small-sized screw pump 21 of the axial-flow type is housed in the pump section 4. The screw pump 21 comprises a shaft 22 and a vane 23 and it is of the single spiral type. The shaft 22 is supported by a bearing 16 and connected to the motor 15.

The casings 12 and 13 of the pump and drive sections 4 and 5 are welded to each other or made as a single unit, so that the heat of the casing 13 of the drive section 5 can be transmitted to the casing 12 of the pump section 4 through heat conduction. Therefore, heat created by the motor 15 is transmitted to the casing 12 of the pump section 4 through the casing 13 and radiated from the casing 12 into blood. The temperature of the drive section 5 can be thus prevented from rising. Further, the drive section 5 is covered by heat-insulating material 8. This can prevent the anatomy of that area of the human body in which the drive section 5 is embedded from being broken or burnt at low temperature by the heat created by the motor 15.

According to this example of the artificial heart, a control means 16 and a power battery 17 are housed in the drive section 5. The power battery 17 is connected to the terminal 10 and regularly charged by a charger (not shown) which is electromagnetically connected to the terminal 10 through the skin H of the human body.

According to this example, the control means 16 controls the artificial heart variously. Namely, a pressure detector 25 of the thin type is attached to the outer circumference of the pump section 4, for example. Further, a detector 26 for detecting the number of rotations of the motor 15, a temperature detector 27, a humor detector 28 for detecting humors such as blood entered into the drive section 5, and the like are housed in the drive section 5. Signals are sent from these detectors to the control means 16, which responds to these signals to add various kinds of controls to the artificial heart according to a program previously stored.

For example, the number of heartbeats of the human heart A is detected responding to the changing signal which is applied from the pressure detector 25 to denote the pressure in the left ventricle. The number of rotations of the motor 15 is changed responsive to the number of heartbeats thus detected, so that the amount of blood fed into the aorta through the artificial heart can be changed responsive to the number of heartbeats of the human heart.

Further, when the shrinking force of the left ventricle B of the human heart A lowers to thereby reduce the amount of blood fed into the aorta through the left ventricle B itself, the pressure in the left ventricle B which expands to the greatest extent rises. Therefore, this state of the left ventricle B is detected by the pressure detector 25 and the number of rotations of the motor 15 is increased so as to compensate the reduction of blood which is fed into the aorta through the left ventricle B of the human heart A. As the result, the amount of blood fed can be kept such a level as needed.

Furthermore, in a case where the temperature of the motor 15 rises to an abnormal value or the casing 13 of the drive section 5 or the seal of the bearing 19 is damaged to allow humors such as blood to enter into the drive section 5, this state is judged in response to the signal applied from the temperature or humor detector 27 or 28 and alarm signal which tells us the occurrence of abnormality can be provided, sounding a buzzer, flickering or vibrating a lamp or sending electromagnetic alarm signal to the external control means.

Figs. 3 through 5 show various kinds of screw pumps employed by the first example of the artificial heart 1.

As described above, the artificial heart of the present invention is intended to insert its pump section 4 into the left ventricle B of the human heart A. It is therefore preferable that the pump section 4 has a volume smaller than that of the left ventricle B obtained when this left ventricle B shrinks to the greatest extent. This can be satisfactorily realized even by the screw pump 21 shown in Fig. 2 and provided with the single vane 23. However, it is preferable that the volume of the pump section 4 is made as small as possible because the pump section 4 is inserted into the heart of the human body. In order to make the pump section 4 smaller-sized, therefore, it is needed that the screw pump is made higher in speed and efficiency.

To meet these needs, a screw pump 21a shown in Fig. 3 is arranged to have three sheets of

vanes 23a which are attached round the shaft 22 in a triple spiral. This screw pump 21a can be made smaller in size but larger in capacity.

According to another screw pump 21b shown in Fig. 4, the outer diameter of a circle drawn by its vane 23b becomes larger as it come nearer to its front end. The inner diameter of a casing 12b is naturally tapered in this case to house the vane 23b therein. In the case of the screw pump 21b, the distribution of pressure in the casing 12b can be made uniform in the axial direction of the casing 12b and the occurrence of cavitation on both sides of the vane 23b can be prevented. The screw pump 21b can be thus made higher in speed.

According to a further screw pump 21c shown in Fig. 5, the pitch of a vane 23c is made larger as it comes nearer to its front end. In the case of the screw pump 21c, the occurrence of cavitation can also be prevented same as seen in the case of the one shown in Fig. 4. This enables the screw pump 21c to be made higher in speed.

The screw pump may be a combination of those ones shown in Figs. 3 through 5. For example, its outer diameter and pitch may be made larger as it comes nearer to its front end, as shown in Figs. 4 and 5.

The pump section 4 may not necessarily be provided with the one of those screw pumps which are shown above in the case of the present invention.

For example, Figs. 6 through 9 show a second example of the artificial heart according to the present invention, in which the pump section 4 houses therein a single screw pump of the eccentric type. A screw groove 32 having an elliptic section is formed in a casing 12d and a rotor 31 of the spiral type having a circular section is fitted into the screw groove 32. When rotated, the rotor 31 reciprocates while sliding in the screw groove 32 and a space 33 formed by the rotor 31 and the inner face of the screw groove 32 is successively moved to the front end of the screw section 4 in the axial direction thereof, as shown in Figs. 7 through 9, to thereby feed blood into the aorta. The pump of this type creates no pulse while it is under operation.

Fig. 10 shows a third example of the artificial heart according to the present invention, in which the front end nozzle 7 is tilted relative to the center line of the pump section 4.

Axial center lines of the left ventricle B, of the aorta valve F and of the aorta G of the human heart are usually aligned with one another. It may be therefore arranged in this case that the pump section 4 and the front end nozzle 7 are on a same axial center line. Depending upon the person who uses the artificial heart, particularly in the case where the person is an old, one of the axial center lines of the left ventricle and of the aorta is sometimes tilted relative to the other at an angle. When the front end nozzle 7 is tilted relative to the pump section 4 at this angle in this case, as shown in Fig. 10, it can be accurately positioned in the centers of the aorta and of the aorta valve not to damage the function of the aorta valve.

Although description has been made on the case where the artificial heart is inserted into the left ventricle of the human heart, the artificial heart may be inserted into the right ventricle thereof.

Fig. 11 shows the artificial heart inserted into the right ventricle J of the human heart A. In Fig. 11, capital letter I represents the right atrium, K the pulmonary valve, and L the pulmonary artery. Needless to say, dimension, shape and others of the pump section 4 of the artificial heart are designed in this case to match those of the right ventricle J, pulmonary valve X and pulmonary artery L.

Figs. 12 and 13 show a third example of the artificial heart according to the present invention, in which an axial-flow pump of the propeller type is housed in the pump section 4.

In Fig. 12, reference numeral 41a denotes a stator vane and 42a propellers.

In the case of the axial-flow pump shown in Fig. 13, that portion of the casing 12 which corresponds to propellers is made larger in diameter. Reference numeral 41b represents a stator vane and 42b propellers.

The arrangement of each of the above-described examples according to the present invention may be changed to have other various functions needed as the artificial heart. The control means, the power battery and the like may be located outside the human body, for example. Further, it is preferable from the viewpoint of radiation that the casing of the pump section and the screw pump housed in the pump section are made of metal. When they are made of metal, heparin coating is applied to their parts which are contacted with blood so as to make them antithrombo-characteristic. Coating of polyurethane, pyritocarbon or the like, for example, is vapor-deposited on them.

The artificial heart is embedded in the human body. If necessary, therefore, it may be arranged that some of its parts are made by so soft material as not to damage the organ of the human body. For example, the front end nozzle of the pump section may be made by soft material such as polyurethane so as to more effectively prevent the aorta valve from being damaged.

Claims

1. An auxiliary artificial heart of the embedded-in-body type embedded in one of the ventricles

of the heart of a human body, characterized

by an apex cordis area ring (2) fixedly embedded in a cut-out apex cordis area (C) of the human heart;

by an artificial heart body (3) inserted into the human heart, passing through the apex cordis area ring (2), and including a pump section (4) and a drive section (5) for driving the pump section, said pump section (4) including a cylindrical pump of the axial-flow type driven by the drive section (5) to suck blood through the base portion of the pump section (4) and discharge it through the front end thereof;

by a nozzle (7) provided at the front end of the pump section and having a diameter smaller than that of the pump section; and

in that said pump section (4) is inserted into one of ventricles (B, J), passing through the apex cordis area ring (2), while said front end nozzle (7) is inserted into the aorta (G or L) through the aorta valve (F) of the human heart, and that blood in the ventricle is fed into the aorta through the front end nozzle (7) by means of the pump section (4).

2. The auxiliary artificial heart of the embedded-in-body type according to claim 1, characterized in that said apex cordis area ring (2) is fixedly embedded in the apex cordis area (C) of the left ventricle (B) while said pump section (4) is inserted into the left ventricle (B).

3. The auxiliary artificial heart of the embedded-in-body type according to claim 1, characterized in that said apex cordis area ring (2) is fixedly embedded in the apex cordis area (C) of the right ventricle (J) while said pump section (4) is inserted into the right ventricle (J).

4. The auxiliary artificial heart of the embedded-in-body type according to claim 1, characterized in that the volume of said pump section (4) is smaller than that of the ventricle (B or J) of the human heart obtained when it shrinks to the greatest extent.

5. The auxiliary artificial heart of the embedded-in-body type according to claim 1, characterized in that said pump section (4) includes a pump of the screw type.

6. The auxiliary artificial heart of the embedded-in-body type according to claim 1, characterized in that said front end nozzle (7) is tilted relative to the pump section (4) to match an angle which is formed by the axial direction of the ventricle of the human heart in which the artificial heart is embedded, and by the axial direction of the aorta.

7. The auxiliary artificial heart of the embedded-in-body type according to claim 1, characterized in that the front end of said front end nozzle (7) is fitted into a positioning ring (8) which serves to position the front end nozzle (7) at a predetermined position of the aorta or pulmonary valve (F or K).

8. The auxiliary artificial heart of the embedded-in-body type according to claim 1, characterized in that said drive section (5) is connected to a control means (16) which serves to control the operation of the drive section (5), depending upon the state of the human heart.

9. The auxiliary artificial heart of the embedded-in-body type according to claim 8, characterized in that said control means (16) is housed in the drive section (5).

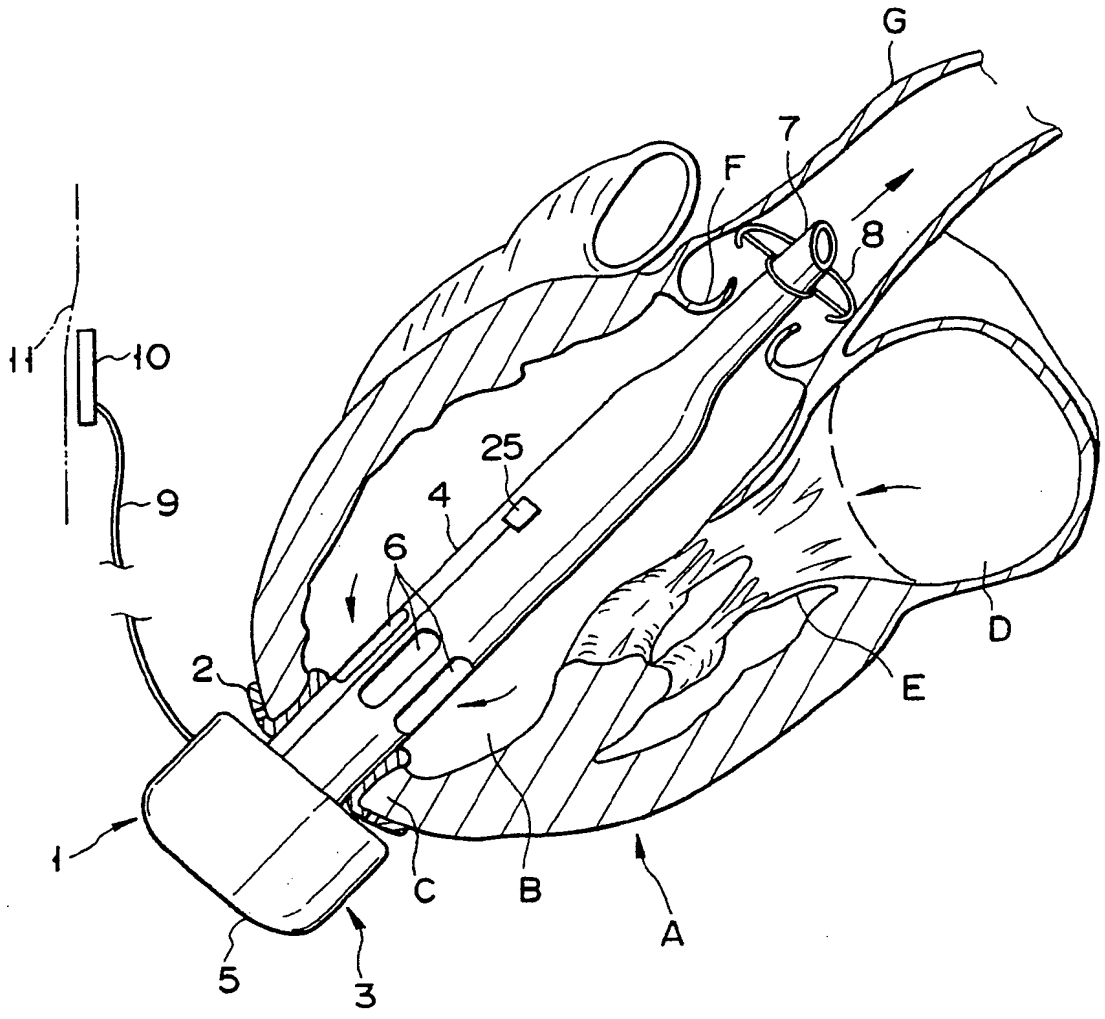

FIG. 1

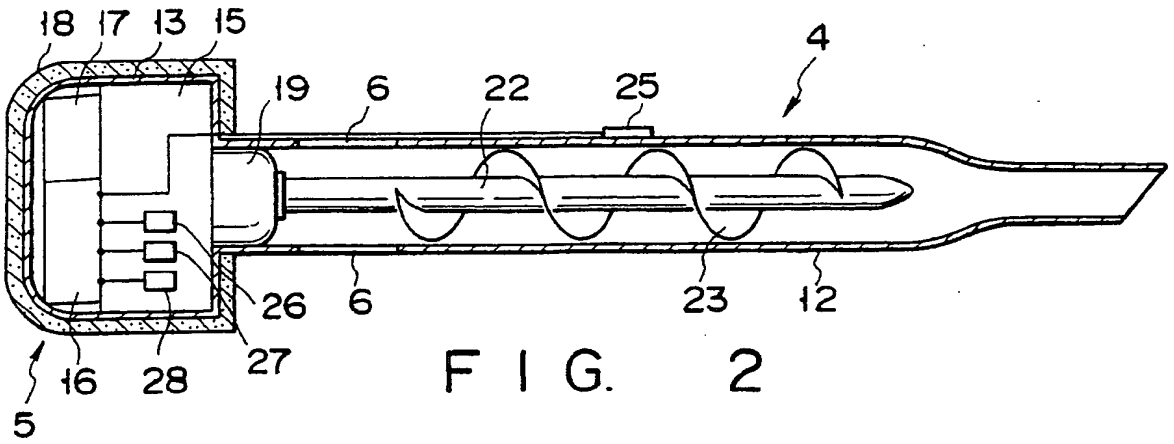

FIG. 2

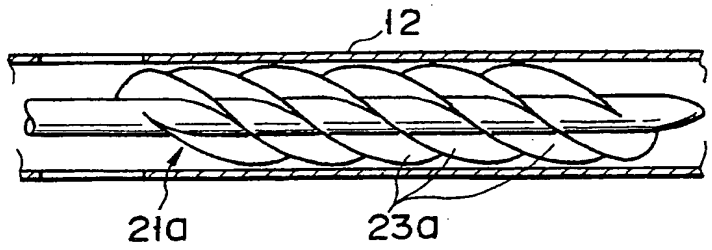

FIG. 3

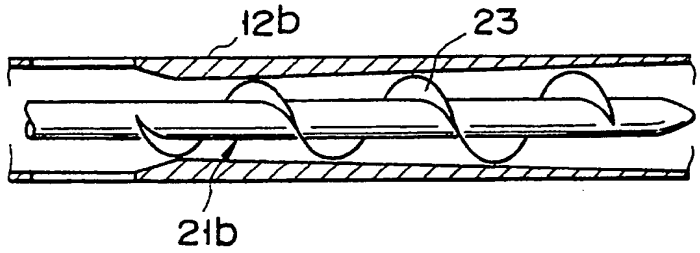

FIG. 4

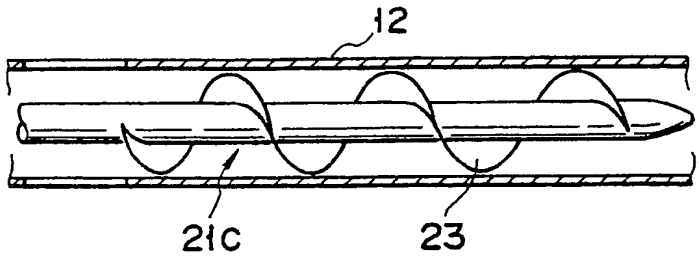

FIG. 5

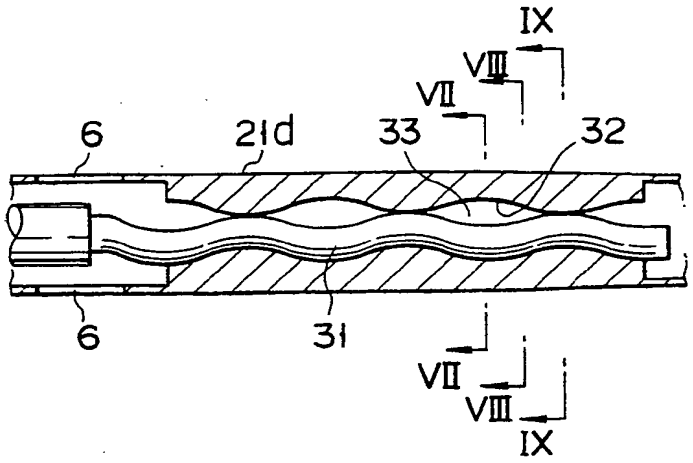

FIG. 6

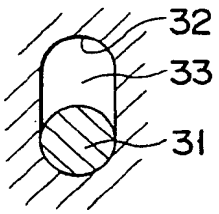

FIG. 7

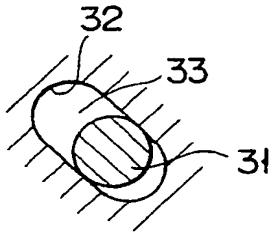

FIG. 8

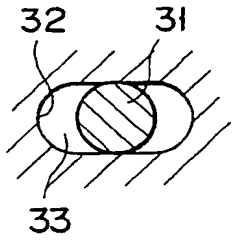

FIG. 9

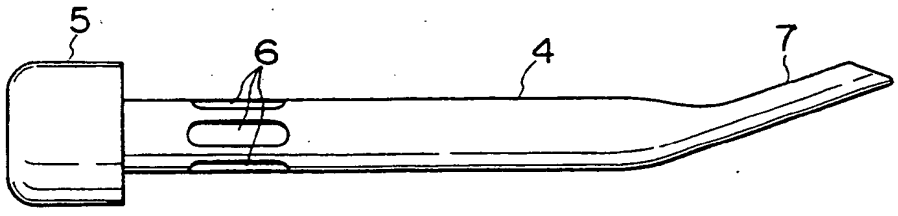

FIG. 10

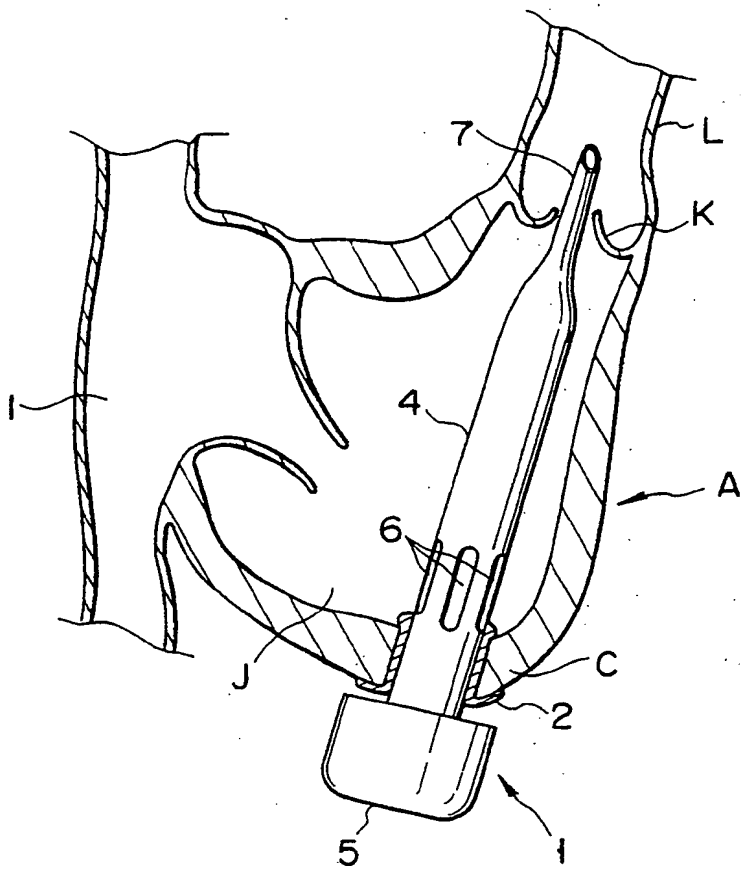

FIG. 11

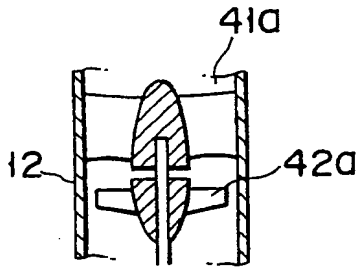

FIG. 12

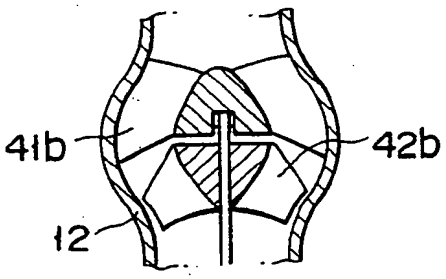

FIG. 13

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 91 10 3427

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	FR-A-1 503 906 (ZACOUTO) * page 1, left column, line 1 - line 13 * * page 3, left column, line 7 - line 31; claim A; figure 1 *	1	A 61 M 1/12
A	US-A-4 753 221 (KENSEY ET AL) * column 1, line 49 - line 63 * * column 4, line 26 - line 28 * * abstract; figures 2,6 *	1	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of search	Examiner
The Hague	24 May 91	GIMENEZ BURGOS R.

CATEGORY OF CITED DOCUMENTS

X: particularly relevant if taken alone
Y: particularly relevant if combined with another document of the same catagory
A: technological background
O: non-written disclosure
P: intermediate document
T: theory or principle underlying the invention

E: earlier patent document, but published on, or after the filing date
D: document cited in the application
L: document cited for other reasons

&: member of the same patent family, corresponding document